DEPARTMENT OF HEALTH & HUMAN SERVICES
Food and Drug Administration
New England District

94894d

One Montvale Avenue
Stoneham, Massachusetts 02180
(781) 596-7700
FAX: (781)596-7896

WARNING LETTER

NWE-29-04W

VIA FEDERAL EXPRESS

July 7, 2004

Ms. Lilly D'Alelio
President and Owner
Lilly's Gastronomia Italiana, Inc.
208 Main Street
Everett, MA 02149-5736

Dear Ms. D'Alelio:

We inspected your seafood processing facility, Lilly's Gastronomia Italiana, Inc., located at 208 Main Street, Everett, MA on February 11 and 12, 2004. We found that you have a serious deviation from the Seafood Hazard Analysis and Critical Control Point (HACCP) regulation, Title 21 Code of Federal Regulations, Part 123 (21 CFR 123). In accordance with 21 CFR 123.6 (g), failure of a processor to have and implement a HACCP plan that complies with this section or otherwise operate in accordance with the requirements of this part, renders the fishery products processed there adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. 342(a)(4). Accordingly, your seafood ravioli products, specifically your lobster ravioli products, are adulterated, in that the product has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. You may find the Act and the seafood HACCP regulation through links in FDA's home page at www.fda.gov.

The serious deviation observed was as follows:

> You must conduct a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur and you must have a written HACCP plan to control any food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6(a) and (b). However, your firm does not have a HACCP plan for the lobster ravioli you routinely manufacture at this location.

During the inspection we observed the manufacturing operations for your lobster ravioli and collected a copy of the product label. Our review of this label revealed that this product is misbranded within the meaning of Section 403(i)(2) of the Act (21 USC 343(i)(2)). The ingredient statement of your label for lobster ravioli fails to declare all the component ingredients of several main ingredients which themselves contain two or more ingredients, as required by 21 CFR 101.4(b)(2). For example:

> Your firm utilizes imitation crabmeat as an ingredient. This imitation crabmeat product lists pollock, cod and/or whiting, wheat starch, egg whites, soybean oil, as well as other ingredients on its label. Your label for lobster ravioli fails to identify any of these component ingredients on your label. This requirement may be met either by parenthetically listing the component ingredients after the common or usual name of the main ingredient, or by listing the component ingredients without listing the common or usual name of the main ingredient itself. Under the first alternative, the component ingredients must be listed in descending order of predominance within the parenthesis; and under the second alternative, the component ingredients must be listed in descending order of predominance in the finished food. This deviation is of particular concern, since some of the listed ingredients are known allergens, for example wheat starch, and egg whites.

Undeclared ingredients that are known allergens are of particular concern to the agency. FDA has received an increasing number of reports concerning consumers who have experienced adverse reactions following exposure to an allergenic substance in foods. For sensitive individuals, the presence of allergens in food is potentially life threatening. Ingredients that are among the most commonly known to cause serious allergic responses are milk, eggs, fish, crustaceans, tree nuts, wheat, peanuts, soybeans, and derivatives of these products.

Refer to 21 CFR Part 101 for all our labeling requirements. You may find a link to these regulations, as well as further explanation of FDA's food labeling requirements, through links in FDA's home page at www.fda.gov.

We may take further action if you do not promptly correct the violations described above. For instance, we may take further action to seize your product(s) and/or enjoin your firm from operating.

Please respond in writing within fifteen (15) working days from your receipt of this letter. Your response should outline the specific things you are doing to correct the violations described above. You should include in your response any documentation, such as your HACCP plan, or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deficiencies.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with all applicable statutes and regulations enforced by the FDA. You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations.

You may direct your reply to Karen N. Archdeacon, Compliance Officer, at the address noted above. If you have any questions concerning this matter, please contact Ms. Archdeacon at (781) 596-7707.

Sincerely,

Gail T. Costello
District Director
New England District Office